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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/544,108	SHERMAN, KENNETH ELIOT	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed May 4, 2007 in response to the Office Action of January 24, 2007 is acknowledged and has been entered. Claims 7, 8, 10-17, 19-24, and 26 have been canceled. Claims 1, 3-6, and 25 are under examination. The finality of the Office action of January 24, 2007 is withdrawn and the prosecution is thereby reopened. Any inconvenience I regretted.

Claim Rejections - 35 USC § 103

Rejection of claims 7, 8, 10-17, 19-24 under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (of record in IDS of May 6, 2002) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and further in view of Horecker (US Patent 4,614,731) **is moot** because Applicant canceled the claims.

Rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Virologica Sinica, 1990, Vol. 5, p. 69-73) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and Horecker (US Patent 4,614,731) as applied to claims 7, 8, 10-17, 19-24 and further in view of Moody (US Patent 5,273,963) **is moot** because Applicant canceled the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (Virologica Sinica, 1990, Vol. 5, p. 69-73) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and Moody et al. (US Patent 5,273,963).

Claims are drawn to a method of treating a mammal infected with hepatitis C virus comprising administering an anti-hepatitis C effective amount of interferon-α, concurrently or sequentially with administering thymosin-α. Interferon is interferon α-2b produced by recombinant DNA technology. The range of interferon administered is between one million and about three million units per administration. The dose of thymosin-α is about 1500 to about 1700 microgram. The thymosin fragment is selected from the group consisting of C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20.

Huang et al. teach combining interferon- α and thymosin in antiviral amounts for human treatment of HBV infection (see the entire document, particularly page 8). Huang dos not teach using the same composition for treatment of HCV infection. Hoofnagle et al. teach using two to five million units of recombinant interferon-α-2b in treatment of HCV infection, but does not teach using thymosin- α in combination with IFN-α-2b (see page 260). However based on the pathogenesis of the infection caused by HBV versus HCV, where both viruses of distinct families cause virtually identical liver disease, and based on the teaching of Hoofnagle, the person of ordinary skill in the art would have been motivated to treat HCV infection with the composition of Huang comprising interferon- α and thymosin. It is also noted that it is well recognized in the art that interferons, including interferon-α, interfere with virus replication regardless what type of virus is a cause of infection. Thus because the activity of interon-α is not virus type specific, based on the knowledge of the antiviral activity of IFN-α against one virus,

the ordinary artisan would have been motivated to treat another viral infection with IFN-α. Thymosin- α is known for its immunopotentiating effect as taught by Moody (see column 3, lines 1-18). It is also well known in the art that thymosin acts as immunopotentiator to induce interferon α, regardless of type of viral infection. Moody also teaches the currently claimed thymosin fragments, such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20 fragment and their significance for therapeutic use (see column 6, lines 17-21). Thus, at the time when the current invention was made the thymosin fragments that have therapeutic significance, such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20 have been known in the art.

It would have been obvious to one of ordinary skill in the art to use Moody's thymosin fragments and Hoofnagle's interferon α-2b in the composition of Huang to treat HCV infection of Hoofnagle.

One would have been motivated to use the thymosin fragments such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20, in the composition comprising thymosin and alpha interferon, because Moody teaches that these particular thymosin fragments have been identified to have therapeutic significance. With respect to particular doses of thymosin-α, it would have been within the ability of ordinary artisan to adjust the doses of thymosin-α in the composition used. Thus the doses of compositions would have been obvious absent any unexpected results.

One would have had a reasonable expectation of success to use particular thymosin fragments in Huang's composition because those thymosin fragments have been identified and made available to one of ordinary skill in the art at the time the current invention was made.

Therefore the claimed method would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

5/26/07

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